

Before the
Administrative Hearing Commission
State of Missouri



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|-----------------------------|---|----------------|
| MISSOURI BOARD OF PHARMACY, |) | |
| |) | |
| Petitioner, |) | |
| |) | |
| vs. |) | No. 12-0699 PH |
| |) | |
| ULDIS PIRONIS, |) | |
| |) | |
| Respondent. |) | |

DECISION ON RECONSIDERATION

Uldis Pironis' pharmacist license is subject to discipline for violating drug statutes and regulations of this state, including lawful regulations adopted pursuant to Chapter 338 RSMo, and for allowing one of his employees to practice pharmacy who was not eligible to do so.

Procedure

On April 20, 2012, the Missouri Board of Pharmacy ("the Board") filed a complaint seeking our determination that there is cause to discipline Pironis' license. On June 1, 2012, Pironis filed a motion for more definite statement. We granted the motion on July 6, 2012. On July 16, 2012, the Board filed an amended complaint, and on July 25, 2012, Pironis answered the amended complaint. On January 15, 2013, Pironis filed a motion to consolidate this case with *Missouri Board of Pharmacy v. Jefferson City Apothecary* ("the Apothecary"), number 12-0697 PH, for the hearing of the two cases. On January 17, 2013, we granted Pironis's motion. On

March 6, 2013, we convened a hearing. Loretta Schouten represented the Board. Johnny K. Richardson and Jamie J. Cox represented Pironis.

This case became ready for our decision when Pironis and the Apothecary (collectively, “Respondents”) filed their last written argument on April 25, 2013. On September 9, 2013, we issued a combined decision in this case and case number 12-0697, in which we struck the Board’s pleadings in the two cases as a sanction. On September 27, 2013, the Board filed a motion to reconsider that decision, asking us to reinstate the portions of the pleadings in the two cases that related to the Board’s 2011 investigations of Pironis and the Apothecary.¹ Respondents filed suggestions in opposition to the motion on October 4, 2013. We granted the motion to reconsider on October 7, 2013.

Commissioner Marvin O. Teer, Jr., having read the full record including all the evidence, renders the decision on reconsideration.²

Findings of Fact

1. Pironis is a Missouri-licensed pharmacist whose license was current and active at all relevant times.
2. Pironis was the pharmacist-in-charge (“PIC”) of the Apothecary at all relevant times.
3. Pironis had extensive training and experience in pharmacy that included compounding, retail, management, and store ownership. He served on the Medicaid Drug Review Board, has spoken at continuing education and other seminars, and served as a preceptor and adjunct professor in schools of pharmacy.

¹ As noted below under “Pleading matters,” the Board’s cases against Pironis and the Apothecary arose from two discrete investigations—one based on an inspection conducted by the Board’s inspectors in 2010, and the other based on the incidents, which occurred on April 29, 2011, that we describe in our Findings of Fact below.

² Section 536.080.2, RSMo 2000; *Angelos v. State Bd. of Regis’n for the Healing Arts*, 90 S.W.3d 189, 192-93 (Mo. App., S.D. 2002). Statutory references are to RSMo 2012 Supp. unless otherwise indicated.

4. At all relevant times, the Apothecary compounded and dispensed drugs and medicines.
5. For about 13 years prior to the date of the hearing, Pironis employed a pharmacy technician named Ginger Stratman.
6. Because he knew he would not be in Jefferson City on April 29, 2011, Pironis arranged, before that date, for another pharmacist to work in the Apothecary.
7. However, on April 29, 2011, the other pharmacist did not report for work due to a family illness. When informed that the other pharmacist had not reported for work, Pironis instructed Apothecary staff to close the Apothecary, but to leave the doors open so that customers could come in and learn why they could not pick up their prescriptions.
8. On that day, Stratman was working at the Apothecary when the Apothecary received a call from Dr. Tamara Hopkins, who requested that the Apothecary prepare a chemotherapy drug, Vidaza, for intravenous administration.
9. Stratman contacted Pironis to tell him of Dr. Hopkins' request.
10. Pironis contacted Hopkins and told her that the Apothecary could not compound the drug because there was no pharmacist there to check it.
11. Hopkins replied that she needed the drug right away. Pironis suggested that Stratman could compound the drug at Dr. Hopkins' office, but it was decided that Stratman would compound the drug at the Apothecary and take it to Dr. Hopkins' office.
12. Stratman compounded the drug and delivered it to Dr. Hopkins' office.
13. The Board first learned of the above-stated events that occurred on April 29, 2011 ("the April 29 incident") from information it had received that someone in the Apothecary was practicing pharmacy without a license when a pharmacist was not on duty.

14. As a result of receiving that information, Sid Werges, an investigator for the Board, went to the Apothecary on May 2, 2011, where he learned of the April 29 incident.

Pleading Matters

The Board's amended complaint against Pironis alleges, in some detail, the following actions, all of which arose from an inspection of the Apothecary by the Board's inspectors on September 21, 2010:

- Patient-specific compounded prescriptions that were returned to the Apothecary's active inventory for future dispensing without preparing batch logs, in violation of 20 CSR 2220-2.400(7)(A)(D);³
- Labeling a compound of Guaifenesin 300mg/Phenylephrine 10mg as "SR" for sustained release without analytical data to prove it had sustained release characteristics, in violation of 20 CSR 2220-2.400(12);⁴
- Compounding a number of products for office stock, in violation of 20 CSR 2220-2.400(12);⁵
- Compounding 200-capsule batches of Policosanol 30mg, a commercially available product, without documented authorization in violation of 20 CSR 2220-2.400(9);⁶
- The expiration dates for ingredients used in compounded products were shorter than the expiration dates for a number of compounded products, in violation of 20 CSR 2220-2.400(4), (8)(A);⁷
- The Apothecary dispensed prescriptions from misbranded lots and after the expiration dates of the ingredients for several products (no regulation was shown that these actions allegedly violated);⁸
- The Apothecary used expired ingredients to compound drug products in violation of §§ 196.015, 196.095, 196.100 RSMo, and 20 CSR 2220-2.400(8)(A) with regard to several products;⁹
- The Apothecary dispensed prescriptions from misbranded lots in violation of §§ 196.015, 196.095, 196.100 RSMo, and 20 CSR 2220-2.400(8)(A) with regard to several products;¹⁰ and
- The Apothecary dispensed prescriptions from misbranded lots in violation of §§ 196.015, 196.095, 196.100 RSMo, and 20 CSR 2220-2.400(8)(A) with regard to several products.¹¹

³ Amended complaint ¶ 10a. All references to the CSR are to the Missouri Code of State Regulations as current with amendments included in the Missouri Register through the most recent update.

⁴ Amended complaint ¶ 10b.

⁵ *Id.* ¶ 10c.

⁶ *Id.* ¶ 10d.

⁷ *Id.* ¶ 12.

⁸ *Id.* ¶ 13.

⁹ *Id.* ¶ 14.

¹⁰ *Id.* ¶ 15.

¹¹ *Id.* ¶ 16.

However, due to the Board's failure to comply with Respondents' discovery request regarding the September 21 inspection, we barred the Board from presenting evidence at the hearing regarding that inspection. As a result, the Board abandoned the allegations set out above.

Evidentiary Matters

Respondents objected to Werges' testimony regarding statements allegedly made by Stratman and another Apothecary employee, Jessica Dickey, to him.¹² The Board argued that such statements were admissible under the employee/agent exception to the hearsay rule, citing among other authorities *State Hwy. Comm'n v. Howard Const. Co.*¹³ Here is what the Court of Appeals said in that case:

A narrative statement by an employee of past events is not admissible against the employer unless the admissions are made within the scope of the employee's employment; *and* to be within the scope of his duties, the employee usually must have some executive capacity.^[14]

(Emphasis added.) In this case, while it is arguable as to whether Stratman's statements were made within the scope of her employment, the Board failed to show that she had any executive capacity.

The Board also argued that Respondents failed to timely object to Werges' statement about what Stratman and Dickey said, citing the portions of the transcript at p. 64, lines 5-13, and p. 65, lines 1-11. We reproduce the relevant portion of the transcript here, starting at p. 63, line 22:

Q Okay. So what information did you learn about what occurred on April 29?

A She told me that Uldis Pironis, the pharmacist-in-charge, was in Chicago and that he had made arrangements for another pharmacist to work on April 29; but because of illness in his family, he was not able to show up. And so the technicians were in

¹² Board brief p. 2.

¹³ 612 S.W.2d 23 (Mo. App., W.D. 1981).

¹⁴ *Id.* at 26.

communication with Mr. Pironis. And Ms. Stratman told me that Mr. Pironis told her to, you know, close the pharmacy but leave the doors open so people could come in, and they could explain to them about, you know, their prescriptions and why they couldn't pick them up, because there was no pharmacist on duty. And then she began to explain to me what she and the other technician, Jessica Dickey, did while they were there that day. She told me that Dickey did some –

MR. RICHARDSON: Your Honor, I'm going to object that this calls for hearsay.

The rules regarding timeliness of an objection have been stated as follows:

To preserve an alleged error relating to the overruling of an objection, it is necessary that an objection be timely made, and usually this necessitates that the objection be made at the earliest possible opportunity in the progress of the case so that the trial judge may have an opportunity to correct, or set right, that which is later to be claimed to be wrong. An untimely objection amounts to a waiver of that objection. Only when there is no opportunity to object to questionable testimony—e.g., the witness responded too quickly to an improper question for an objection to be immediately interposed—is a later objection permissible.^[15]

In *Oak Bluff Condo. Ass'n*, the case cited immediately above, counsel asked the witness one question that elicited a hearsay response, and then asked three more questions before opposing counsel raised a hearsay objection. The Court of Appeals held that the trial court did not err in overruling the objection as untimely.¹⁶

In this case, however, counsel for Respondents objected while Werges was answering the first question—admittedly, with a narrative answer that included three hearsay statements (“Ms. Stratman told me that...,” “And then she began to explain to me...,” and “She told me that...”), but we must decide whether the objection was made later than “...the earliest possible opportunity in the progress of the case so that the trial judge may have an opportunity to correct,

¹⁵ *Oak Bluff Condo. Ass'n v. Oak Bluff Partners, Inc.*, 263 S.W.3d 714, 719-20 (Mo. App., S.D. 2008) (internal citations omitted).

¹⁶ *Id.* at 721.

or set right, that which is later to be claimed to be wrong.” We think Respondents’ objection was timely by that standard. Therefore, we sustain Respondents’ objection to Werges’ statement.

Conclusions of Law

We have jurisdiction to hear the Board’s complaint.¹⁷ The Board has the burden of proving by a preponderance of the evidence that Pironis committed an act for which the law allows discipline.¹⁸

The Board alleges that Pironis’s license is subject to discipline under the following provisions of § 338.055.2:

The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

* * *

¹⁷Section 338.055.2 .

¹⁸*Missouri Real Estate Comm’n v. Berger*, 764 S.W.2d 706, 711 (Mo. App., E.D. 1989).

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government[.]

§ 338.055.2(5)- Incompetency, Misconduct,
Gross Negligence, Misrepresentation, and Fraud

Incompetency

Incompetency is a general lack of professional ability, or a lack of disposition to use an otherwise sufficient professional ability, to perform in an occupation.¹⁹ We follow the analysis of incompetency in a disciplinary case from the Supreme Court, *Albanna v. State Bd. of Reg'n for the Healing Arts*.²⁰ Incompetency is a “state of being” showing that a professional is unable or unwilling to function properly in the profession.²¹ We find no lack of professional ability in Pironis’s actions. To the contrary, he had extensive training and experience in pharmacy, as was recognized by his speaking engagements at continuing education and other seminars, as well as his role as an adjunct professor in schools of pharmacy. Specifically, in this case, he was well aware of the issues involved with compounding and dispensing drugs without his being present during those events and discussed them knowledgably with Dr. Hopkins. Neither do we find any lack of professional ability with regard to the Apothecary-- which would, if found, subject Pironis’ license to discipline due to his being pharmacist-in-charge of the Apothecary.

On the other hand, Pironis’ allowing Stratman to compound the drug does show a lack of disposition to use his otherwise professional ability. However, this isolated incident does not show a “state of being” showing his inability or unwillingness to function properly in his profession. Therefore, we find no ground for discipline against Pironis for incompetency.

¹⁹ *Tendai v. Missouri State Bd. of Reg’n for the Healing Arts*, 161 S.W.3d 358, 369 (Mo. banc 2005).

²⁰ 293 S.W.3d 423 (Mo. banc 2009).

²¹ *Id.* at 435.

Misconduct

Misconduct means “the willful doing of an act with a wrongful intention[;] intentional wrongdoing.”²² While the Board makes much of Pironis’s alleged willfulness in his actions, the Board failed to provide any evidence of wrongful intention. Therefore, we find no ground for discipline against Pironis for misconduct.

Gross Negligence

The Board argued in its brief that Pironis committed gross negligence, but failed to plead it. We cannot find cause for discipline for uncharged conduct.²³

We find no ground for discipline against Pironis for gross negligence.

Misrepresentation and Fraud

Misrepresentation is a falsehood or untruth made with the intent and purpose of deceit.²⁴ Neither Pironis nor the Apothecary made any misrepresentation with regard to the April 29 incident. The Board also argued in its brief²⁵ that Pironis and the Apothecary committed fraud. Fraud is “an intentional perversion of truth to induce another ... to act in reliance upon it.”²⁶ However, the Board did not allege fraud in its amended complaint. Even if it had been charged, we found no intent, no perversion of truth, and no inducement to act in reliance upon anything Pironis communicated. We also find no falsehood or untruth uttered by Pironis. We find no ground for discipline against Pironis for misrepresentation or fraud.

Conclusion Regarding § 338.055.2(5)

We find no ground for discipline against Pironis under § 338.055.2(5).

²² *Missouri Bd. for Arch’ts, Prof’l Eng’rs & Land Surv’rs v. Duncan*, No. AR-84-0239 (Mo. Admin. Hearing Comm’n Nov. 15, 1985) at 125, *aff’d*, 744 S.W.2d 524 (Mo. App., E.D. 1988).

²³ *Missouri Dental Bd. v. Cohen*, 867 S.W.2d 295, 297 (Mo. App., W.D. 1993).

²⁴ MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 794 (11th ed. 2004).

²⁵ ¶ 64.

²⁶ *Hernandez v. State Bd. of Regis’n for the Healing Arts*, 936 S.W.2d 894, 899 n.2 and n.3 (Mo. App. W.D. 1997).

Section 338.055(6) & (15)- Violation of Laws and Regulations

The Board argues that Pironis's license is subject to discipline for violation of the following statutes and regulations:

Section 338.010

Section 338.010.1 defines the practice of pharmacy in relevant part as follows:

The "practice of pharmacy" means the...receipt, transmission, or handling of [medical prescription] orders or facilitating the dispensing of such orders;...the compounding, dispensing, [and] labeling...of drugs...pursuant to medical prescription orders;...and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter.

Stratman, a pharmacy technician, compounded and dispensed the chemotherapy drug order. None of these things was done by Pironis or under his supervision. Therefore, if the statute is read alone, Stratman (and any other employees of the Apothecary who dispensed the product) practiced pharmacy without a license. A pharmacy technician such as Stratman is, by statutory definition, a person who assists a pharmacist in the practice of pharmacy.²⁷ Furthermore, some of the regulations Pironis is accused of violating expressly provide for someone other than a licensed pharmacist to compound,²⁸ dispense,²⁹ or label³⁰ a drug, medicine, or poison, so long as the product is inspected and verified by a licensed pharmacist. Clearly, then, the Board's regulations contemplate that non-pharmacists, and non-licensed pharmacists,

²⁷ Section 338.013.1.

²⁸ "Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold." 20 CSR 2220-2.010(1)(B). (Emphasis added.)

²⁹ *Id.*

³⁰ "The pharmacist personally shall inspect and verify the accuracy of...the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist." *Id.*

may compound, dispense, and label drugs, medicines, or poisons, so long as their products are inspected and verified by a licensed pharmacist.

We read 20 CSR 2220-2.010(1) (which we discuss in more detail below) as creating conditions under which a pharmacist's supervision of others actually doing the compounding and dispensing, and testing of the final product before it is dispensed, constitutes the practice of pharmacy so as to satisfy § 338.010, even if the pharmacist did not do the compounding and dispensing him or herself. However, Pironis did not supervise and test the product as the regulation requires. Therefore, we conclude that Stratman engaged in the unlicensed practice of pharmacy by her actions of April 29, 2011, and did so at Pironis's instruction. Therefore, Pironis violated § 338.010.

Section 338.210.5

The Board argues that Pironis, as pharmacist-in-charge, is subject to discipline for violation of § 338.210.5, which reads:

If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

If a law was violated, the violation occurred “in connection with or adjunct to the preparation or dispensing of a prescription or drug order.” Therefore, we may deem Pironis's license (due to his being pharmacist-in-charge) subject to discipline for such acts if they occurred in connection with or adjunct to the preparation or dispensing of a drug order.

As we set out elsewhere, we conclude that Pironis's license is subject to discipline for violation of § 338.010, 20 CSR 2220-2.010(1), and 20 CSR 2220-2.200(12)(A), all of which occurred while he was pharmacist-in-charge. Furthermore, all such violations occurred in connection with or adjunct to the preparation or dispensing of a drug order—specifically,

Stratman's preparation of Vidaza for Dr. Hopkins' patient. Therefore, Pironis violated § 338.210.5.

20 CSR 2220-2.010(1)

The Board argues that Pironis violated 20 CSR 2220-2.010(1), which provides in relevant part:

(1) The word medicine or medicines is a word similar or of like import to the words pharmacist, pharmacy, apothecary shop, chemist shop, drug store, druggist and drugs, and no person shall carry on, conduct or transact a business under a name which contains, as part of the name, the word medicine or medicines, unless the place of business is supervised by a licensed pharmacist.

(A) At all times when prescriptions are compounded in a pharmacy or other establishments holding a Missouri pharmacy permit, there shall be on duty and present in that place of business a pharmacist licensed in Missouri as provided by law. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be considered on duty and present as long as all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patients or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. When there is no pharmacist on duty, no prescription will be compounded, dispensed or otherwise provided and the public will be advised that no pharmacist is on duty by means of signs stating this fact. The signs will be displayed prominently on the doors of all entrances and the prescription counter of the pharmacy and the signs will be composed of letters of a minimum height of two inches (2").

(B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. In any Class J: Shared Service pharmacy where a permit is maintained at a location for the purpose of remote dispensing as defined in 20 CSR 2220-2.900 the pharmacist may be on duty and present as long as

all required electronic connection requirements are maintained and the pharmacist is accessible at all times to respond to patient's or other health professionals' inquiries or requests pertaining to drugs dispensed through the use of the automated pharmacy system. The pharmacist personally shall inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.³¹

Paragraph (A) requires a pharmacist to be on duty and present *in the pharmacy* whenever prescriptions are compounded in the pharmacy. Paragraph (B) requires a pharmacist to be *physically present within the confines of the dispensing area* when a person other than a pharmacist compounds, dispenses, or in any way provides any drug, medicine, or poison pursuant to a lawful prescription. (Emphasis added.) Paragraph (B) also requires the pharmacist to “personally...inspect and verify the accuracy of the contents of, and the label after it is affixed to, any prescribed drug, medicine or poison compounded or dispensed by a person other than a licensed pharmacist.”

In *Board of Pharmacy v. Jack A. Levison & Forum Center Pharmacy*,³² Levison was the pharmacist-in-charge for Forum Center Pharmacy when an unlicensed person filled two prescriptions while he (Levison) was away from the pharmacy. Also, while Levison was away from the pharmacy, several other errors were made. While the Board alleged a violation of 4 CSR 220-2.010(1)(B),³³ this Commission found that Levison did not know that the unlicensed person filled the prescriptions in his (Levison's) absence. Therefore, we held that Levison was not subject to discipline under 338.055.2(6) or (10) because he did not assist or enable the unlicensed person to violate the regulation.

³¹ The Board also alleged in its complaint against Pironis that paragraph (O) of 20 CSR 2220-2.010(1) was violated. By a plain reading, paragraph (O) refers only to a permit holder, i.e., a pharmacy, being subject to discipline for violation of the pharmacy laws by one of its employees.

³² No. 94-001353PH (Missouri Admin. Hearing Comm'n, Jan. 18, 1995).

³³ The predecessor regulation to 20 CSR 2220-2.010(1)(B).

In this case, however, Pironis not only knew that Stratman was compounding and dispensing a prescription in his absence, but she did those things at Pironis's instruction. Furthermore, paragraphs (A) and (B) required Pironis to be physically present in the pharmacy (paragraph (A)), and within the confines of the dispensing area, when Stratman compounded the drug (paragraph (B)). Pironis was neither in the Apothecary's dispensing area nor anywhere else in the Apothecary when Stratman was compounding and dispensing the chemotherapy drug. Therefore, he violated this regulation.

20 CSR 2220-2.090(2)

The Board argues that Pironis failed to perform the duties and responsibilities of a pharmacist-in-charge as set out in 20 CSR 2220-2.090(2), as follows:

The responsibilities of a pharmacist-in-charge, a minimum, will include:

* * *

(E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of controlled substances are in compliance with state and federal laws;

* * *

(G) All labeling requirements are complied with according to section 338.059, RSMo, federal laws where required and board regulations governing auxiliary labeling of drugs and devices;

* * *

(N) The pharmacist-in-charge will be responsible for the supervision of all pharmacy personnel, to assure full compliance with the pharmacy laws of Missouri;

* * *

(P) Policies and procedures are in force to insure safety for the public concerning any action by pharmacy staff members or within the pharmacy physical plant;

* * *

(V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;

(W) Assure full compliance with all state and federal drug laws and rules;

* * *

(Y) Assure that all state and federal laws concerning drug distribution and control are complied with and that no violations occur that would cause a drug or device or any component thereof to become adulterated or misbranded[.]

We agree with the Board that Pironis failed to adhere to his responsibilities with regard to paragraphs (E), (N), and (W), which constitute three separate ways of saying that the PIC is obligated to ensure that the laws are followed and that pharmacy personnel follow such laws.

However, we disagree with the Board's allegations contained in the other paragraphs for the following reasons:

(G) This paragraph requires compliance with the labeling requirements set out in § 338.059,³⁴ "federal laws where required," and "board regulations governing auxiliary labeling of drugs and devices." However, the Board failed to set out which (if any) federal laws contained labeling requirements that may have been violated, and said nothing about any of its regulations governing auxiliary labeling of drugs and devices. Thus, we are left with § 338.059, which provides:

1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug upon which is typed or written the following information:

(1) The date the prescription is filled;

(2) The sequential number;

³⁴ RSMo 2000.

- (3) The patient's name;
- (4) The prescriber's directions for usage;
- (5) The prescriber's name;
- (6) The name and address of the pharmacy;
- (7) The exact name and dosage of the drug dispensed;

(8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";

(9) When a generic substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist's records as required in section 338.100.

2. The label of any drug which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.

The only evidence put forward regarding labeling was Werges' testimony that the prescription had been "run through [the pharmacy's computer] system" the day before the product was prepared and dispensed, which included preparing the label.³⁵ Our review of the record indicates no other time when the actual process of preparing the label was brought up in testimony. Unlike the process of compounding or dispensing the drug, there is no requirement that the pharmacist be physically present when the label is generated or applied to the drug's container.

(P) We found nothing in the evidence suggesting that Pironis had not put policies and procedures in force to ensure the public's safety concerning the actions of pharmacy staff members or within the pharmacy's physical plant. We consider the Board's inclusion of this paragraph to be analogous to its argument, unsupported by evidence, that the April 29 incident was just the tip of the iceberg and that Pironis operated an unsafe establishment.

(V) There was no evidence that outdated drugs were involved in the April 29 incident.

³⁵ Tr. 87-88.

(Y) There was no evidence that state or federal laws concerning drug distribution and control were not complied with.

Therefore, we find that Pironis violated his duties as a pharmacist-in-charge with regard to paragraphs (E), (N), and (W).

20 CSR 2220-2.200(12)(A)

The Board argues that Pironis violated Regulation 20 CSR 2220-2.200(12)(A), which provides:

End-Product Evaluation.

(A) Risk Level 1: The final product must be inspected for container leaks, integrity, solution cloudiness or phase separation, particulates in solution, appropriate solution color, and solution volume. The pharmacist must verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of products for any particulate and/or foreign matter must be used as part of the inspection[.]

The Board argues that Pironis and the Apothecary violated this regulation by allowing technicians to work in the pharmacy without a licensed pharmacist present. We agree. The requirement that a pharmacist “verify that the product was compounded accurately as to the ingredients, quantities, containers, and reservoirs” was not met. Therefore, Pironis violated this regulation.

20 CSR 2220-2.400(8)(A)

The Board argues that Pironis violated 20 CSR 2220-2.400(8)(A), which provides:

(8) Management of Compounding.

(A) A pharmacist dispensing any compounded drug is responsible for ensuring that the product has been prepared, labeled, controlled, stored, dispensed and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation of products, with key factors including at least the following general principles:

1. Personnel are capable and qualified to perform their assigned duties;
2. Ingredients used in compounding have their expected identity, quality and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;
3. Reasonable assurance that processes are always carried out as intended or specified;
4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and
5. All finished products, as a condition of release, must be individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

The Board argues that by allowing technicians to prepare prescriptions, compound drugs, and dispense chemotherapy compounds without a pharmacist present, Pironis and the Apothecary violated this regulation. The Board impliedly asserts that because the letter of the law was not followed when Stratman compounded the drug without his presence, the drug was not prepared, labeled, controlled, stored, dispensed and distributed properly, and that Pironis had failed his responsibility to ensure “that quality is built into the preparation of products.” We think the Board failed to prove that the quality was not built into the product, or that Pironis failed to ensure that this was the case. To the contrary, the precaution and care shown by Pironis met the letter of this regulation—which, unlike 20 CSR 2220-2.010(1)(A) or (B), does not require the physical presence of a pharmacist while the product is compounded. Therefore, Pironis did not violate this regulation.

20 CSR 2220-2.700(1)

The Board argues that Pironis violated 20 CSR 2220-2.700(1), which provides:

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

(B) A person may be employed as a technician once a completed application and the required fee is received by the board. The board will provide either a registration certificate that shall be conspicuously displayed or a letter of disqualification preventing the applicant's employment within a pharmacy.

(C) Information required on the application shall include, but is not limited to--

1. The name, phone number, and residential address of the applicant;
2. Full-time and part-time addresses where the applicant will be employed as a technician;
3. Information concerning the applicant's compliance with state and federal laws, as well as any violations that could be considered grounds for discipline as outlined in section 338.013.5, RSMo;
4. One (1) two-inch by two-inch (2" x 2") frontal view portrait photograph of applicant; and
5. Proof of fingerprinting as required by 20 CSR 2220-2.450.

(D) A copy of the application must be maintained by the applicant at the site(s) of employment during and until notice of registration or disqualification is received by the applicant and must be readily retrievable for review by the board of pharmacy or the board's representatives.

However, the Board failed to specify how Pironis violated this regulation, and we will not speculate as to its interpretation.

Conclusion Regarding § 338.055.2(6) and (15)

Pironis's license is subject to discipline under § 338.055.2(6) and (15) for his violation of §§ 338.010, 338.210.5, 20 CSR 2220-2.010(1), 20 CSR 2220-2.090(2)(E), (N), and (W), and 20 CSR 2220-2.200(12)(A).

Section 338.055.2(10)- Assisting or Enabling any Person to Practice Pharmacy who is not Eligible to do so

Section 338.055.2(10) states that a pharmacist's license may be disciplined for:

Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter[.]

As we discuss above under "Section 338.010," Pironis allowed Stratman, a pharmacy technician and not a pharmacist, to practice pharmacy as it is defined in § 338.010. Furthermore, she practiced pharmacy under Pironis's direction and with his approval. Pironis's license is subject to discipline for violation of § 338.055.2(10).

Section 338.055.2(13)- Professional Trust or Confidence

The Board argues that Pironis's license is subject to discipline for violation of patients' trust or confidence. Professional trust is the reliance on the special knowledge and skills that professional licensure evidences.³⁶ It may exist not only between the professional and his clients, but also between the professional and his employer and colleagues.³⁷ Because we have no evidence that Dr. Hopkins' patient had any relationship or communication with Pironis or the Apothecary, our inquiry is limited to the relationship between Pironis and Dr. Hopkins.

³⁶ *Trieseler v. Helmbacher*, 168 S.W.2d 1030, 1036 (Mo. 1943).

³⁷ *Cooper v. Missouri Bd. of Pharmacy*, 774 S.W.2d 501, 504 (Mo. App., E.D. 1989).

We find no violation of professional trust here. To the contrary, Pironis alerted Dr. Hopkins of the issue and tried to persuade the doctor to seek the drug elsewhere, and when that did not work, accommodated the doctor's wishes to obtain the drug that day.

Pironis's license is not subject to discipline under § 338.055.2(13).

Other Unpleaded Conduct

In addition to the unpleaded conduct discussed above, the Board's brief raised several accusations of conduct that it asserted were grounds for discipline, but were not pleaded in its amended complaint—or, in some cases, were not pleaded for anything other than the September 21 incident, which was not considered by us once we disallowed evidence in support thereof. We set those unpleaded instances out below.

Alleged Violation of 20 CSR 2220-2.018(1)

The Board's brief argued that Pironis directed the Apothecary's pharmacy technicians to violate 20 CSR 2220-2.018(1) in that "the initials or name of the pharmacist responsible for processes in dispensing or compounding of the prescription" were not affixed to the prescription.³⁸ However, violation of this regulation was not raised as a ground for discipline.

Alleged Collusion Between Pironis and Dr. Hopkins

The Board's brief also argued that "circumstances indicate collusion between Pironis and Dr. Hopkins to compound and dispense chemotherapy drugs, knowing that such drugs would be compounded without a pharmacist present and would never be reviewed by a pharmacist."³⁹ In addition to presenting no evidence in support, the Board did not allege it in its amended complaint.

³⁸ Board's brief ¶ 56.

³⁹ *Id.* ¶ 46.

Respondents allegedly kept inaccurate and incomplete compounding logs.

The Board's brief argued that Respondents allegedly kept inaccurate and incomplete compounding logs.⁴⁰ In addition to presenting no evidence in support of this allegation with regard to the April 29 incident, it failed to allege this in its amended complaint.

Pironis allegedly caused the Apothecary to violate § 195.060.1.

The Board's brief argued that Pironis caused the Apothecary to violate § 195.060.1.⁴¹ However, the Board did not allege this in its complaint against Pironis.

It was Pironis's alleged "habit, routine, and practice" to violate Missouri law.

The Board's brief argued that Pironis had the "habit, routine, and practice" to violate Missouri law.⁴² This allegation arose from Pironis's testimony that, by the Board's interpretation, the April 29 incident was not the first time one of the Apothecary's technicians had compounded and dispensed a product without his participation. However, we note (as the Board did not) that Pironis clarified his testimony, stating that while the technicians might have compounded a product while he was at lunch, the product was never dispensed without his checking it.⁴³ In any case, the Board failed to allege this matter in its complaint against Pironis.

Pironis allegedly demonstrated unethical and unprofessional conduct in knowingly directing technicians to practice pharmacy.

The Board's brief made this argument. However, it was not only not raised in either complaint, but the Board failed to state how it constituted grounds for discipline. Our review of the relevant laws also failed to find any such ground.

Pironis allegedly violated 21 U.S.C. §§ 331 and 353(b).

The Board made this allegation in its brief, but did not plead it.

⁴⁰ *Id.* ¶ 39.

⁴¹ *Id.* ¶ 49-50.

⁴² *Id.* ¶¶ 50-54.

⁴³ Tr. 134.

Summary

We find cause to discipline Pironis' license under § 338.055.2(6), (10), and (15). We find no cause to discipline his license under § 338.055.2(5) or (13), or under the various alleged but unpleaded grounds for discipline.

SO ORDERED on November 6, 2013.

\s\ Marvin O. Teer, Jr.

MARVIN O. TEER, JR.

Commissioner